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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/475,822	06/07/1995	MARC ALIZON	3495.0010-24	4214

22852 7590 12/20/2002

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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 12/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/475,822	Applicant(s) ALIZON ET AL.	
	Examiner Jeffrey Fredman	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Double Patenting

1. The double patenting rejections are withdrawn in view of the claim amendments in this case and the related cases.

Claim Objections

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires that when new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Here, two claims are numbered "41".

Misnumbered claim 41 been renumbered 42. Specifically, the second claim "41", drawn to the kit of claim 41, was renumbered 42.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 35, 37, 39, 41, 43 and 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Chang et al (U.S. Patent 6,001,977).

Chang teaches in vitro diagnostic methods for detecting the presence or absence of HIV-1 virus in a biological sample (column 9, lines 25-62) comprising:

contacting said biological sample with a nucleic acid probe of HIV-1 selected from the HIV sequence (column 9, lines 25-62 and column 10, line 65 to column 11, line 32),

where the specific sequence is disclosed as SEQ ID NO: 4, for example (columns 19-28).

And detecting the formation of hybrids in the biological sample (column 9, lines 25-62).

Chang further teaches the compositions of these nucleic acids (column 9, lines 25-62) as well as HTLV-I and II negative control sequences (column 9, lines 25-62).

The alignment of the Query HIV sequences of Chang and the subject sequences of the present application in the region between nucleotides 4000 and 9000 are presented below.

```
Query: 4010 ttccctacaatccccaaagtcaaggagtagtagaatctatgaataaagaattaaagaaaa 4069
            ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 4197 ttccctacaatccccaaagtcaaggagtagtagaatctatgaataaagaattaaagaaaa 4256
pol     856  I  P  Y  N  P  Q  S  Q  G  V  V  E  S  M  N  K  E  L  K  K

Query: 4070 ttataggacaggtaagagatcaggctgaacatcttaagacagcagtacaaatggcagtat 4129
            ||||||| ||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 4257 ttataggccaggtaagagatcaggctgaacatcttaagacagcagtacaaatggcagtat 4316
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pol    876  I  I  G  Q  V  R  D  Q  A  E  H  L  K  T  A  V  Q  M  A  V


Query: 4130 tcatccacaattttaaaagaaaannnnnnnnnnnnnnntacagtgcaggggaaagaatag 4189
            ||||||||||||||||||||||                ||||||||||||||||||||||
Sbjct: 4317 tcatccacaattttaaaagaaaaggggggattgggggtacagtgcaggggaaagaatag 4376
pol    896  F  I  H  N  F  K  R  K  G  G  I  G  G  Y  S  A  G  E  R  I


Query: 4190 tagacataatagcaacagacatacaaactaaagaattacaaaaacaaattacaaaaattc 4249
            ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 4377 tagacataatagcaacagacatacaaactaaagaattacaaaaacaaattacaaaaattc 4436
pol    916  V  D  I  I  A  T  D  I  Q  T  K  E  L  Q  K  Q  I  T  K  I


Query: 4250 aaaattttcgggtttattacagggacagcagaaatccactttggaaaggaccagcaaagc 4309
            |||||||||||||||||||||||||||||| ||||||||||||||||||||||||||
Sbjct: 4437 aaaattttcgggtttattacagggacagcagagatccactttggaaaggaccagcaaagc 4496
pol    936  Q  N  F  R  V  Y  Y  R  D  S  R  D  P  L  W  K  G  P  A  K


Query: 4310 tcctctggaaaggtgaaggggcagtagtaatacaagataatagtgacataaaagtagtgc 4369
            ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 4497 tcctctggaaaggtgaaggggcagtagtaatacaagataatagtgacataaaagtagtgc 4556
pol    956  L  L  W  K  G  E  G  A  V  V  I  Q  D  N  S  D  I  K  V  V


Query: 4370 caagaagaaaagcaaagatcattagggattatggaaaacagatggcaggtgatgattgtg 4429
            ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 4557 caagaagaaaagcaaagatcattagggattatggaaaacagatggcaggtgatgattgtg 4616
pol    976  P  R  R  K  A  K  I  I  R  D  Y  G  K  Q  M  A  G  D  D  C


Query: 4430 tggcaagtagacaggatgaggattagaacatggaaaagtttagtaaaacaccatatgtat 4489
            ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 4617 tggcaagtagacaggatgaggattagaacatggaaaagtttagtaaaacaccatatgtat 4676
pol    996  V  A  S  R  Q  D  E  D ^^^


Query: 4490 gtttcagggaaagctaggggatggttttatagacatcactatgaaagccctcatccaaga 4549
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Query: 4550 ataagttcagaagtacacatcccactaggggatgctagattggtaataacaacatattgg 4609
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Query: 5390 ttctctatcaaagcagtaagtagtacatgtaatgcaacctatacaaatagcaatagtagc 5449
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orfQ   35     S  L  S  K  Q ^^^


Query: 5450 attagtagtagcaataataatagcaatagttgtgtggtccatagtaatcatagaatatag 5509
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env    1                                                    K  E  Q


Query: 5570 agacagtggcaatgagagtgaaggagaaatatcagcacttgtggagatgggggtggagat 5629
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Query: 6174 ctcagtcattacacaggcctgtccaaaggtatcctttgagccaattcccatacattattg 6233
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env    211    S  V  I  T  Q  A  C  P  K  V  S  F  E  P  I  P  I  H  Y  C

Query: 6234 tgccccggctggttttgcgattctaaaatgtaataataagacgttcaatggaacaggacc 6293
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Query: 6354 actgctgttaaatggcagtctggcagaagaagaggtagtaattagatctgccaatttcac 6413
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Sbjct: 6555 actgctgttgaatggcagtctagcagaagaagaggtagtaattagatctgccaatttcac 6614
env    271    L  L  L  N  G  S  L  A  E  E  E  V  V  I  R  S  A  N  F  T
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Query: 6414 agacaatgctaaaaccataatagtacagctgaaccaatctgtagaaattaattgtacaag 6473
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Sbjct: 6615 agacaatgctaaaaccataatagtacagctgaaccaatctgtagaaattaattgtacaag 6674
env    291    D  N  A  K  T  I  I  V  Q  L  N  Q  S  V  E  I  N  C  T  R


Query: 6474 acccaacaacaatacaagaaaaagtatccgtatccagagaggaccagggagagcatttgt 6533
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Sbjct: 6675 acccaacaacaatacaagaaaaagtatccgtatccagaggggaccagggagagcatttgt 6734
env    311    P  N  N  N  T  R  K  S  I  R  I  Q  R  G  P  G  R  A  F  V


Query: 6534 tacaataggaaaaataggaaatatgagacaagcacattgtaacattagtagagcaaaatg 6593
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Sbjct: 6735 tacaataggaaaaataggaaatatgagacaagcacattgtaacattagtagagcaaaatg 6794
env    331    T  I  G  K  I  G  N  M  R  Q  A  H  C  N  I  S  R  A  K  W


Query: 6594 gaataacactttaaaacagatagatagcaaattaagagaacaatttggaaataataaaac 6653
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Sbjct: 6795 gaatgccactttaaaacagatagctagcaaattaagagaacaatttggaaataataaaac 6854
env    351    N  A  T  L  K  Q  I  A  S  K  L  R  E  Q  F  G  N  N  K  T


Query: 6654 aataatctttaagcagtcctcaggaggggacccagaaattgtaacgcacagttttaattg 6713
           ||||||||||||||| ||||||||||||||||||||||||||||||||||||||||||||||
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env    371    I  I  F  K  Q  S  S  G  G  D  P  E  I  V  T  H  S  F  N  C


Query: 6714 tggaggggaatttttctactgtaattcaacacaactgtttaatagtacttggtttaatag 6773
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Sbjct: 6915 tggaggggaatttttctactgtaattcaacacaactgtttaatagtacttggtttaatag 6974
env    391    G  G  E  F  F  Y  C  N  S  T  Q  L  F  N  S  T  W  F  N  S


Query: 6774 tacttggagtactaaagggtcaaataacactgaaggaagtgacacaatcaccctcccatg 6833
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Sbjct: 6975 tacttggagtactgaagggtcaaataacactgaaggaagtgacacaatcacactcccatg 7034
env    411    T  W  S  T  E  G  S  N  N  T  E  G  S  D  T  I  T  L  P  C


Query: 6834 cagaataaaacaaattataaacatgtggcaggaagtaggaaaagcaatgtatgcccctcc 6893
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Sbjct: 7035 cagaataaaacaatttataaacatgtggcaggaagtaggaaaagcaatgtatgcccctcc 7094
env    431    R  I  K  Q  F  I  N  M  W  Q  E  V  G  K  A  M  Y  A  P  P


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```
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Sbjct: 7155 tggtaataacaacaatgggtccgagatcttcagacctggaggaggagatatgagggacaa 7214
env    471    G  N  N  N  N  G  S  E  I  F  R  P  G  G  G  D  M  R  D  N

Query: 7014 ttggagaagtgaattatataaatataaagtagtaaaaattgaaccattaggagtagcacc 7073
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Sbjct: 7215 ttggagaagtgaattatataaatataaagtagtaaaaattgaaccattaggagtagcacc 7274
env    491    W  R  S  E  L  Y  K  Y  K  V  V  K  I  E  P  L  G  V  A  P

Query: 7074 caccaaggcaaagagaagagtggtgcagagagaaaaaagagcagtgggaataggagcttt 7133
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Sbjct: 7275 caccaaggcaaagagaagagtggtgcagagagaaaaaagagcagtgggaataggagcttt 7334
env    511    T  K  A  K  R  R  V  V  Q  R  E  K  R  A  V  G  I  G  A  L

Query: 7134 gttccttgggttcttgggagcagcaggaagcactatgggcgcagcgtcaatgacgctgac 7193
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Query: 7194 ggtacaggccagacaattattgtctggtatagtgcagcagcagaacaatttgctgagggc 7253
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env    551    V  Q  A  R  Q  L  L  S  G  I  V  Q  Q  Q  N  N  L  L  R  A

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Query: 7314 aagaatcctggctgtggaaagatacctaaaggatcaacagctcctggggatttggggttg 7373
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Query: 7374 ctctggaaaactcatttgcaccactgctgtgccttggaatgctagttggagtaataaatc 7433
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Sbjct: 7575 ctctggaaaactcatttgcaccactgctgtgccttggaatgctagttggagtaataaatc 7634
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Sbjct: 7635 tctggaacagatttggaataacatgacctggatggagtgggacagagaaattaacaatta 7694
env    631    L  E  Q  I  W  N  N  M  T  W  M  E  W  D  R  E  I  N  N  Y
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Query: 7494 cacaagcttaatacactccttaattgaagaatcgcaaaaccagcaagaaaagaatgaaca 7553
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env    651    T  S  L  I  H  S  L  I  E  E  S  Q  N  Q  Q  E  K  N  E  Q


Query: 7554 agaattattggaattagataaatgggcaagtttgtggaattggtttaacataacaaattg 7613
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Sbjct: 7755 agaattattggaattagataaatgggcaagtttgtggaattggtttaacataacaaattg 7814
env    671    E  L  L  E  L  D  K  W  A  S  L  W  N  W  F  N  I  T  N  W


Query: 7614 gctgtggtatataaaattattcataatgatagtaggaggcttggtaggtttaagaatagt 7673
            |||||||||||||||| ||||||||||||||||||||||||||||||||||||||||||
Sbjct: 7815 gctgtggtatataaaaatattcataatgatagtaggaggcttggtaggtttaagaatagt 7874
env    691    L  W  Y  I  K  I  F  I  M  I  V  G  G  L  V  G  L  R  I  V


Query: 7674 ttttgctgtactttctgtagtgaatagagttaggcagggatattcaccattatcgtttca 7733
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env    711    F  A  V  L  S  I  V  N  R  V  R  Q  G  Y  S  P  L  S  F  Q


Query: 7734 gacccacctcccaatcccgaggggacccgacaggcccgaaggaatagaagaagaaggtgg 7793
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Query: 7794 agagagagacagagacagatccattcgattagtgaacggatccttagcacttatctggga 7853
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env    751    E  R  D  R  D  R  S  I  R  L  V  N  G  S  L  A  L  I  W  D


Query: 7854 cgatctgcggagcctgtgcctcttcagctaccaccgcttgagagacttactcttgattgt 7913
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Sbjct: 8055 cgatctgcggagcctgtgcctcttcagctaccaccgcttgagagacttactcttgattgt 8114
env    771    D  L  R  S  L  C  L  F  S  Y  H  R  L  R  D  L  L  L  I  V


Query: 7914 aacgaggattgtggaacttctgggacgcaggggtgggaagccctcaaatattggtggaa 7973
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Sbjct: 8115 aacgaggattgtggaacttctgggacgcaggggtgggaagccctcaaatattggtggaa 8174
env    791    T  R  I  V  E  L  L  G  R  R  G  W  E  A  L  K  Y  W  W  N


Query: 7974 tctcctacagtattggagtcaggagctaaagaatagtgctgttagcttgctcaatgccac 8033
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Query: 8034 agctatagcagtagctgaggggacagatagggttatagaagtagtacaaggagcttatag 8093
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Sbjct: 8235 agccatagcagtagctgagggnacagatagggttatagaagtagtacaaggagcttgtag 8294
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orfF   1                                  D  R  A  W  K  G  F  C  Y  K
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Query: 8154 tgggtggcaagtggtcaaaaagtagtgtggttggatggcctgctgtaagggaaagaatga 8213
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orfF   11   M  G  G  K  W  S  K  S  S  V  V  G  W  P  T  V  R  E  R  M


Query: 8214 gacgagctgagccagcagcagatggggtgggagcagcatctcgagacctagaaaaacatg 8273
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orfF   31   R  R  A  E  P  A  A  D  G  V  G  A  A  S  R  D  L  E  K  H


Query: 8274 gagcaatcacaagtagcaacacagcagctaacaatgctgattgtgcctggctagaagcac 8333
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orfF   51   G  A  I  T  S  S  N  T  A  A  T  N  A  A  C  A  W  L  E  A


Query: 8334 aagaggaggaggaggtgggttttccagtcacacctcaggtacctttaagaccaatgactt 8393
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orfF   71   Q  E  E  E  E  V  G  F  P  L  T  P  Q  V  P  L  R  P  M  T


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orfF   91   Y  K  A  A  V  D  L  S  H  F  L  K  E  K  G  G  L  E  G  L


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Sbjct: 8655 ttcactcccaacgaagacaagatatccttgatctgtggatctaccacacacaaggctact 8714
orfF   111  I  H  S  Q  R  R  Q  D  I  L  D  L  W  I  Y  H  T  Q  G  Y


Query: 8514 tccctgattagcagaactacacaccagggccagggatcagatatccactgacctttggat 8573
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Sbjct: 8715 tccctgattggcagaactacacaccagggccaggggtcagatatccactgacctttggat 8774
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orfF   131  F  P  D  W  Q  N  Y  T  P  G  P  G  V  R  Y  P  L  T  F  G


Query: 8574 ggtgctacaagctagtaccagttgagccagagaagttagaagaagccaacaaaggagaga 8633
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orfF   151  W  C  Y  K  L  V  P  V  E  P  D  K  V  E  E  A  N  K  G  E


Query: 8634 acaccagcttgttacaccctgtgagcctgcatggaatggatgacccggagagagaagtgt 8693
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orfF   171  N  T  S  L  L  H  P  V  S  L  H  G  M  D  D  P  E  R  E  V


Query: 8694 tagagtggaggtttgacagccgcctagcatttcatcacatggcccgagagctgcatccgg 8753
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orfF   191  L  E  W  R  F  D  S  R  L  A  F  H  H  V  A  R  E  L  H  P


Query: 8754 agtacttcaagaactgctgacatcgagcttgctacaagggactttccgctggggactttc 8813
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Sbjct: 8955 agtacttcaagaactgctgacatcgagcttgctacaagggactttccgctggggactttc 9014
orfF   211  E  Y  F  K  N  C ^^^


Query: 8814 cagggaggcgtggcctgggcgggactggggagtggcgagccctcagatcctgcatataag 8873
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Query: 8874 cagctgctttttgcctgtactgggtctctctggttagaccagatctgagcctgggagctc 8933
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Sbjct: 9075 cagctgctttttgcctgtactgggtctctctggttagaccagatttgagcctgggagctc 9134

Score = 2796 bits (1454), Expect = 0.0
Identities = 1477/1489 (99%)
 Strand = Plus / Plus
```

It is noted that with regard to, for example, the sequence region between nucleotides 4487 and 5086 claimed in claim 11, there are two nucleotide differences between the sequences. It is noted that the art recognizes that sequencing errors occur in a range between 0.3 % and 2.5%, as evidenced by Richterich (Genome Research (1998) 8:251-259). However, these error rates are determined using technology that was significantly more advanced than that in 1984, when sequencing error rates were

likely significantly higher. In the 599 nucleotide sequence which is the first sequence of claim 1, two errors would represent approximately a 0.3% error rate. Thus, these sequences are identical within the error range available and the anticipation rejection is proper.

With regard to the kit claims, it is noted that the preamble phrase "a kit" imposes no structural requirements upon the product claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 35-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al (U.S. Patent 6,001,977) as applied to claims 35, 37, 39, 41, 43 and 45 as discussed above and further in view of White et al (U.S. Patent 4,677,054).

Chang teaches the limitations of claims 35, 37, 39, 41, 43 and 45 as discussed above, including detection of HIV-1 using nucleic acid probes by dot blotting.

Chang does not teach the use of labels on the probes.

White teaches labeling probes and hybridization reagents using radioactive labels for detection of nucleic acids including RNA from animal tissue by hybridization (column 2, lines 6-34).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to combine the method of White with the method of Change because White states that the method is widely applicable, stating "It will be obvious to those skilled in the art that the method of the present invention is general in scope and can be used for DNA and mRNA-like analysis of all sorts of biological specimens (column 2, lines 40-44)." Further motivation to detect using these methods is provided by White, who notes "Very small amounts of sample can be tested. Furthermore, the samples can be hybridized with multiple probes used in sequence (column 3, lines 2-4)". An ordinary practitioner would have been motivated to use the labels of White to detect HIV as taught by Chang since White says that the method is

broadly applicable, permits the use of small sample amounts and permits detection using multiple different probes to enhance specificity.

Response to Arguments

7. Applicant's arguments filed November 18, 2002 have been fully considered but they are not persuasive.

Applicant argues that a comparison of the sequences of Chang and the present case show that Chang has stop codons which would prevent expression of the ORFs. This argument is not found persuasive for several reasons.

First, it is not simply the sequence which Chang teaches, but the specific DNA entity, the composition, which was in the lab. Because of the issue of sequencing error, addressed in the rejection itself, it is unclear whether these differences between the sequences identified by Applicant represent real differences or simply sequencing error. If the differences are real, as evidenced by a declaration (which is expressly invited), then applicant's argument would be persuasive. However, given the high probability of sequencing errors as discussed above, combined with the knowledge that due to contamination, the virus strain of Chang was the same virus strain as that used by Applicant, the rejections are maintained.

Second, since the claims are comprising, an diagnostic vector which comprises the entirety of the HIV genome would inherently comprise each and every ORF, including those claimed. Since such a vector is within the teaching of Chang, this clearly anticipates the current claims.

Third, to the extent that the argument relies upon the fact that Chang did not correctly identify these open reading frames due to the presence of stop codons, this argument is not persuasive because formation of random fragments as taught by Chang will create the vectors irrespective of whether Chang was aware of the open reading frames or not.

Fourth, to the extent that the argument relies upon actual sequence differences which create different open reading frames, no evidence is on record showing that the sequences are, in fact, different. A declaration which evidenced such a difference in sequence, which directly corresponded to a claim, would be valuable in this application and applicant is expressly invited to provide such a declaration. Currently, there is no evidence which rebuts the position that any differences are the result of sequencing error.

As a final point, it is noted that in this case, there is better evidence than is ordinarily available that the strains sequenced by the two different groups are, in fact, the same since it is clear that the LAI strain is common to both of these applications.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Jeffrey Fredman
Primary Examiner
Art Unit 1637

December 19, 2002